IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION,	:	
Plaintiff,	:	C.A. No. 1:12-cv-01091-LPS
v.	:	
ACTAVIS MID ATLANTIC LLC,	:	
Defendant.	:	

ANSWER, AFFIRMATIVE DEFENSES, and COUNTERCLAIMS OF DEFENDANT ACTAVIS MID ATLANTIC LLC

Defendant Actavis Mid Atlantic, LLC ("Actavis") herewith files its Answer, Affirmative Defenses, and Counterclaims. Actavis responds to the individually numbered paragraphs in Plaintiff's Complaint as follows:

THE PARTIES

1. Actavis lacks information sufficient to admit or deny the allegations of paragraph 1 of Plaintiff's Complaint. The allegations therefore stand denied.

2. Actavis admits the allegations contained in paragraph 2 of the Complaint.

NATURE OF THE ACTION

3. The allegations of paragraph 3 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, Actavis admits that this action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Any remaining allegations requiring a response are denied.

JURISDICTION AND VENUE

4. The allegations of paragraph 4 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, Actavis admits that this

Court has subject matter jurisdiction over Plaintiff's Complaint pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Paragraph 5 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Actavis submits to personal jurisdiction in this District for the limited purpose of the present litigation. Actavis denies the legal sufficiency of Plaintiff's claims and allegations. Actavis further denies that it has infringed Plaintiff's patent. Any remaining allegations requiring a response are denied.

6. Paragraph 6 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Actavis admits that venue is proper in this Court, but denies the legal sufficiency of Plaintiff's claims and allegations. Actavis further denies that it has infringed Plaintiff's patent. Any remaining allegations requiring a response are denied.

7. With respect to Paragraph 7 of the Complaint, Actavis admits that attached as Exhibit A to Plaintiff's Complaint is a copy of U.S. Patent No. 8,236,816 ("the '816 patent"), entitled "2x2x2 Week Dosing Regimen for Treating Actinic Keratosis with Pharmaceutical Compositions Formulated with 3.75% Imiquimod," which on its face states that it was issued on August 7, 2012. Actavis denies that the '816 patent was duly and legally issued. Actavis further denies any remaining allegations of paragraph 7.

8. With respect to Paragraph 8, upon information and belief, according to publicly available information at the United States Food and Drug Administration's ("FDA") website, Actavis understands that Medicis is identified as the holder of New Drug Application No. 22-483 for a topical treatment of clinically typical, visible, or palpable actinic keratoses ("AK") of the full face or balding scalp in immunocompetent adults using 3.75% imiquimod cream, which is sold under the brand name "Zyclara® Cream (3.75%)." Actavis lacks information sufficient to

admit or deny the remaining allegations of paragraph 8 of Plaintiff's Complaint. The allegations therefore stand denied.

9. Actavis lacks information sufficient to admit or deny the allegations of paragraph 9 of Plaintiff's Complaint. The allegations therefore stand denied.

10. Actavis admits that the '816 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Zyclara® Cream (3.75%).

ACTS GIVING RISE TO THIS ACTION

11. Actavis admits that it submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 203-792 under 21 U.S.C. § 355 (j) for 3.75% imiquimod cream ("Proposed Product"). Actavis denies the remaining allegations of Paragraph 11 of Plaintiff's Complaint.

12. Actavis admits that it certified in ANDA No. 203-792 that the claims of the '816 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Actavis Generic Product.

13. Actavis admits that in its Notice Letter dated August 7, 2012, it alleged that claims 1-18 of the '816 patent would not be infringed by the commercial manufacture, use, offer for sale, or sale of the product covered by its ANDA, and that claims 1-18 of the '816 patent are invalid on grounds of obviousness. Actavis lacks information sufficient to admit or deny the remaining allegations of paragraph 13 of Plaintiff's Complaint. The remaining allegations therefore stand denied.

14. Actavis admits that its product that is the subject of ANDA No. 203-792 includes a proposed label for Actavis' product with prescribing information. Actavis otherwise denies any remaining allegations of paragraph 14.

15. Actavis admits that its label indicates that its product is indicated for actinic keratosis and genital warts. Actavis otherwise denies any remaining allegations of paragraph 15.

16. Denied. The proposed label for Actavis' proposed product speaks for itself. Further, Paragraph 16 of the Complaint contains legal conclusions to which no response is required and to the extent a response may be required, Actavis denies the allegations set forth in Paragraph 16.

17. Denied.

18. Denied.

19. Denied.

20. Denied.

GENERAL DENIAL

Unless expressly admitted herein, Actavis denies all remaining allegations contained in Plaintiff's Complaint.

REQUESTED RELIEF

Actavis denies that Plaintiff is entitled to any of the relief that they seek in their Prayer for Relief or otherwise. Specifically, Actavis denies that Medicis is entitled to the findings in sub-parts A and B, and denies that Medicis is entitled to the relief sought in sub-parts C, D, and E.

AFFIRMATIVE DEFENSES

Without admitting or acknowledging that it bears the burden of proof as to any of them, Actavis asserts the following affirmative defenses:

First Affirmative Defense

1. Plaintiff's Complaint fails to state a claim against Actavis upon which relief may be granted.

Second Affirmative Defense

2. The manufacture, use, sale, offer for sale, or importation of Actavis' Proposed Product does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '816 patent either literally or under the doctrine of equivalents. Nor did the filing of Actavis' ANDA No. 203-792 infringe any valid and enforceable claim of the '816 patent either literally or under the doctrine of equivalents.

Third Affirmative Defense

3. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during prosecution of the application that led to the issuance of the '816 patent, the '816 patent is so limited that no claim can be construed as covering the manufacture, use, sale, offer for sale, or importation of Actavis' Proposed Product.

Fourth Affirmative Defense

4. One or more claims of the '816 patent are invalid for failure to meet one or more of the requirements of Title 35, United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

Fifth Affirmative Defense

5. Plaintiff cannot prove that this is an exceptional case justifying award of attorney fees against Actavis pursuant to 35 U.S.C. § 285.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Actavis Mid Atlantic, LLC ("Actavis"), by way of counterclaim against Plaintiff Medicis Pharmaceutical Corporation ("Medicis"), alleges:

THE PARTIES

1. Actavis is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

2. On information and belief, Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. Medicis is engaged in the business of research, development, and sale of pharmaceutical products. These products are sold throughout the United States and the State of Delaware.

JURISDICTION AND VENUE

3. These claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)("MMA")(21 U.S.C. §355(j)).

4. This Court has personal jurisdiction over Plaintiff because they have availed themselves of the rights and privileges of this forum by suing Actavis in this District.

5. On information and belief, Plaintiff maintains a significant business presence in the United States, this State, and this District, through their direct actions, including but not limited to selling, attempting to sell, marketing, and distributing pharmaceutical products in this jurisdiction.

6. Venue is proper under 28 U.S.C. § 1391.

7. Plaintiff is engaged in, and its activities substantially affect, interstate and foreign commerce through the activities referenced herein, some or all of which were conducted through the United States mail and other instrumentalities of interstate commerce and in connection with activities crossing state lines.

FACTUAL BACKGROUND

8. Upon information and belief, Medicis is the current holder of New Drug Application No. 22-483 ("NDA") for a topical treatment of clinically typical, visible, or palpable actinic keratoses ("AK") of the full face or balding scalp in immunocompetent adults using 3.75% imiquimod cream, which is sold under the brand name "Zyclara® Cream (3.75%)." Upon information and belief this product is also indicated for "treatment of external genital and perianal warts (EGW)/condyloma acuminate in patients 12 years or older."

9. Medicis has informed the United States Food and Drug Administration ("FDA") of the following unexpired patent with respect to which Medicis alleges a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of 3.75% imiquimod cream: U.S. Patent No. 8,236,816 ("the '816 patent"). Plaintiff purports to have all rights to sue and recover for any infringement of the '816 patent. This patent is listed by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book" for the FDA. *See* 21 U.S.C. § 355(j)(7).

10. By listing the '816 patent in the Orange Book, Medicis is purportedly representing to the world that this patent covers Zyclara® Cream (3.75%), or a method of using that drug, and that an infringement suit could be alleged against any generic ANDA applicant,

including Actavis, that attempts to seek approval for, and market, a generic version of 3.75% imiquimod cream before the patent's expiration.

11. Actavis holds Abbreviated New Drug Application ("ANDA") No. 203-792 for 3.75% imiquimod cream ("Proposed Product").

12. Actavis filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") certifying that the '816 patent listed in the Orange Book is either invalid, unenforceable or will not be infringed by the manufacture, use or sale of Actavis' Proposed Product. In accordance with 35 U.S.C. § 355(j)(2)(B)(i) and (ii), Actavis mailed Medicis a notice that it had filed such a Paragraph IV certification and provided the factual and legal bases for that certification.

13. In connection with giving notice to Medicis of its Paragraph IV certification, Actavis provided Medicis with an offer of confidential access to its ANDA in accordance with 21 U.S.C. § 355(j)(5)(c)(i)(I)(cc) and (III).

14. On September 4, 2012, Plaintiff sued Actavis in this district alleging infringement of the '816 patent based on Actavis' ANDA No. 203-792.

15. Accordingly, there is an actual, substantial and continuing justiciable case and controversy between Plaintiff and Actavis regarding the '816 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

16. As a result of any exclusion of Actavis from the marketplace, Actavis and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of a lower-priced 3.75% imiquimod cream.

17. This case is exceptional pursuant to 35 U.S.C. § 285 and Actavis is entitled to its reasonable attorneys' fees pursuant to that statute.

FIRST COUNT

18. Actavis repeats and realleges paragraphs 1 through 17 of the counterclaims.

19. Plaintiff has asserted the '816 patent against Actavis. Plaintiff alleges – and Actavis denies – that any valid, enforceable claims of the '816 patent cover the Proposed Product.

20. Actavis has not infringed and will not infringe any valid and enforceable claim of the '816 patent by making, using, selling, offering for sale, marketing, or importing the proposed product.

21. Plaintiff and Actavis have adverse legal interests, and there is a substantial controversy between Plaintiff and Actavis of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '816 patent.

22. Actavis is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of its Proposed Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '816 patent.

SECOND COUNT

23. Actavis repeats and realleges paragraphs 1 through 22 of the counterclaims.

24. The claims of the '816 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101 *et seq.*, including, but not limited to, §§ 102, 103, and/or 112.

25. Plaintiff alleges – and Actavis denies – that the claims of the '816 patent are valid.

26. Plaintiff and Actavis have adverse legal interests, and there is a substantial controversy between them of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the claims of the '816 patent.

27. Therefore, a present, genuine, and justiciable controversy exists between Plaintiff and Actavis regarding, *inter alia*, the validity of the claims of the '816 patent.

28. Actavis is entitled to a judicial declaration that the claims of the '816 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, having fully answered Plaintiff's Complaint, Actavis prays that:

a. A declaratory judgment be entered that all asserted claims of the '816 patent are invalid and unenforceable;

b. A declaratory judgment be entered that Actavis does not and has not infringed, whether directly or indirectly, either literally or under the doctrine of equivalents, nor contributed to nor induced the infringement of the '816 patent;

c. Plaintiff's Complaint be dismissed with prejudice;

d. Plaintiff be awarded no damages;

e. Actavis be awarded its costs and fees, including reasonable attorneys' fees incurred to defend this action; and,

f. Actavis be awarded such other and further relief as the Court deems appropriate.

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